



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 12 1998

Via Federal Express

Warning Letter

Mr. Michael Farris
President & CEO
LaserSight Technologies, Inc.
12249 Science Drive, Suite 160
Orlando, Florida 32826

Dear Mr. Farris:

The Food and Drug Administration (FDA) has reviewed a copy of your advertisement which appeared in the January/February 1998 issue of Refractive Eyecare (copy enclosed), as well as the information on your internet homepage referred to in the advertisement (hard copy enclosed). Both contain statements which constitute serious violations of FDA regulations pertaining to advertisement of investigational devices, 21 Code of Federal Regulations (21CFR) Part 812.7 and to the Federal Food, Drug, and Cosmetic Act (the Act). Excimer lasers are devices as that term is defined in Section 201(h) of the Act. We have also reviewed a copy of the November 13, 1997, letter you sent to owners of what you refer to as "custom-built lasers," with regard to your purchase from IBM of fundamental patents that cover laser vision correction (copy enclosed).

Promotional materials for investigational devices must state **prominently** that they are for use in approved investigational studies only. Moreover, according to 21CFR 812.7(d) a sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator is prohibited from representing that an investigational device is safe and effective for the purposes for which it is being investigated. Thus the following statements, found in Refractive Eyecare, are in violation of the regulations:

"...most advanced laser technology;" "scanning technology...provides smoother ablations and lower acoustic shock waves;" "LaserScan LSX ...with enhanced functionality;" "AccuTrack eye tracking system, which monitors and responds to saccadic and drifting eye movements;" "CeraLase laserhead, which runs cool and produces real time energy stabilization;" "a corneal topography mapping system, ScanLink™ that will help surgeons create customized ablation

Similarly, there are multiple problems with the material that appears on your internet home page which states or implies that the investigational device(s), or procedures using those devices, are safe and/or effective. Some of the problems noted include, but are not limited to, the following:

Under the heading **LASERSCAN 2000™**, the following statements regarding safety and effectiveness are prohibited:

"...precisely removed to produce a finely polished corneal surface;"
"...no rings or ridges are produced;" "smoother ablations...less haze, faster healing, and more stable clinical results;" "homogeneity with elegant simplicity;" "Improves healing and produces improved patient outcomes;" "Low pulse energy and low acoustic shock waves reduce sonic distraction and may provide a lower potential for either induced acoustic trauma or central islands."

Moreover, while you have an approved Investigational Device Exemption (IDE) to study refractive surgery for the treatment of myopia and astigmatism with this laser, you do not have approved IDEs to study hyperopia or LASIK, two treatment areas also mentioned in this section. Their inclusion causes the device to be adulterated according to Section 501(f)(1)(B) of the Act in that it is a Class III device under Section 513(f) and does not have an approved application for premarket approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption under Section 520(g) for these indications.

Under the heading **LASER TRABECULODISSECTION**, a statement that the device is for use in approved investigational studies only is totally lacking. Moreover, the following statements regarding safety and effectiveness are prohibited:

"...revolutionary new technique;" "Potential advantages...1. ...no risk of endophthalmitis. 2....eliminating the need for peribulbar or retrobulbar block. 3. ...done in a minor procedure room. 4. No risk of intraocular bleeding; 5. No risk of anterior chamber collapse. 6. Reduced risk of hypotony and its sequelae,... 7. Eliminates the need for iridectomy;" "...scanning system,...no photo-acoustic shock wave to rupture the very thin membrane remaining;" "...has resulted in

chambers that have remained formed with good blebs and no striate keratopathy."

The internet section describing your "new LaserScan LSX™" causes this device to be adulterated according to Section 501(f)(1)(B) of the Act in that it is a Class III device under Section 513(f) and does not have an approved application for premarket approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption under Section 520(g). Moreover, the following statements regarding safety and effectiveness are prohibited:

"...remarkable level of precision;" "...smooth, polished ablation to help minimize the patient healing response;" "...eye tracking system...for use with LASIK, PRK, or PTK to produce high precision;" "CeraLase laserhead delivers minimum surgery time...minimum stromal 'air time'...stable, long life while being frugal with gases;" "flexible treatment strategies are available to allow the surgeon to correct large ametropic ranges including high myopia, astigmatism and hyperopia;" "...designed to easily transport for multi-site use;" "...runs more efficiently."

The Automated Disposable Microkeratome, mentioned in both your Refractive Eyecare advertisement and in a section on your internet home page, was cleared for marketing as of January 8, 1998. However, the inclusion of the heading "*One Step LASIK*," results in the misbranding of this device according to Section 502(o), in that the labeling included in the clearance of this device did not include its use in the LASIK procedure and a notice or other information respecting this new intended use of the device was not provided to the FDA as required by 21CFR 807.81(a)(3)(ii).

With regard to your letter of November 13, 1997, you offer to apply license fees, for patent infringements that the addressee may have incurred, toward the future purchase of either your disposable keratome (the ADK) or your LS 2000 excimer laser system. At the time the letter was written, neither device was marketable. 21CFR 812.7(a) prohibits the promotion of an investigational device until after FDA has approved the device for commercial distribution.

This letter is not intended to be an all-inclusive list of violations for your products. It is your responsibility to ensure adherence to each requirement of the regulation.

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Failure to promptly correct these violations may result in regulatory action by FDA without further notice. These actions include, but are not limited to, injunction, seizure, and/or civil penalties.

Please inform us, in writing, within 15 days of receipt of this letter, as to the measures you have taken to ensure that all present and future promotional materials comply with the investigational device requirements. Enclosed for your guidance is a copy of the "Guideline for Preparing Notices of Availability of Investigational Medical Devices," as well as pertinent excerpts from the FDA Information Sheets. Please send your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Jean Toth-Allen, Ph.D.

If you have any questions or concerns, feel free to call Jean Toth-Allen at (301) 594-4723, ext. 141.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological
Health

Enclosures